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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/225,080 | 01/04/1999 | JANICE AU-YOUNG | PF-0066-2-DI | 2905 |

7590 03/28/2002
LUCY J BILLINGS
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EXAMINER

CANELLA, KAREN A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 03/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/225,080

Applicant(s)
Au-Young

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 10, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Jan 10, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. ☒ Applicant's reply has overcome the following rejection(s):
see attached
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: none
Claim(s) objected to: none
Claim(s) rejected: 39-42
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☒ Other: PTO-892

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Response to Arguments

1. Claims 39-42 are under consideration.
2. The rejection of claims 39-42 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. Applicant argues that post-filing date reference which overcame the rejection under 35 U.S.C. 101, also overcomes the enablement rejection as the reference teaches that the claimed polypeptide is indeed a stem cell antigen. This has been considered but not found persuasive. The rejection under 35 U.S.C. 101 was removed as applicant alleged that the amino acid sequence of PSCA and SCAH-2 were identical. After examination of post-filing date sequences this was found to be not entirely correct. As indicated in the attached Accession Number 043653, the instant SEQ ID NO:2 has an "X" at position 94, whereas Reiter et al disclosed an "A" at position 94. Thus the instant specification fails to identify the entirety of SCAH-2 as the residue at position 94 is ambiguous. Reiter et al (PNAS, 1998, Vol. 95, pp. 1735-1740) disclose that PSCA, which is identical to the instant SCAH-2 (SEQ ID NO:2) with the exception of residue 94, is a prostate-specific stem cell antigen, the detection of which is diagnostic for both androgen-dependent and androgen-independent prostate cancer. Reiter et al disclose (page 1739, second column, first full paragraph) that although PSCA is a member of the LY-6 gene family the biological function of PSCA is unknown as members of the LY-6 family exhibit diverse cellular functions. Thus, the only utility of SCAH-2 revealed by Reiter et al is in the diagnosis prostate cancer. The instant specification claims utility through membership in the LY-6 family (page 2, lines 20-24) and sequence homology with chicken stem cell antigen 2 (page 6, lines 10-12). However, the instant specification fails to teach the diagnosis of prostate cancer or any other specific cancer based on the detection of SEQ ID NO:2. Page 20, lines 21 to 29 of the specification teaches a method by which SCAH expression can be used to provide a basis for diagnosis. The specification fails to teach the specific disease which is being diagnosed, the type

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of body tissue or fluids which must be obtained, or the overexpression or underexpression or SCAH in the specific disease.


Applicant further argues that the disclosed SCAH-2 is enabled as it is expressed on the surface of stem cells. As the specification does not teach a specific type of stem cell in terms of identifying the cell lineage(s) which arises from said stem cell, or the organ or tissue arising from the proliferation of said stem cells, one of skill in the art would not be able to use an antibody which binds to SCAH-2 in the isolation or detection of stem cells of a particular cell lineage or tissue, as one of skill in the art would not know the bodily tissue from which to isolate said stem cells.

3. The rejection of claim 39 (parts a, b and c) under 35 U.S.C. 102(b) as being anticipated by any of Wilkie et al (Genomics, 1993) or Wray et al (Gene 1993) or Burton (Nature, 1993) or Gama et al (Mol. Microbiol., 1992) or Birkeland (Can J. Microbiol., 1994) or Arendt et al (Appl. Environ. Microbiol., 1994) is withdrawn.

4. The rejection of claims 39 (part d) under 35 U.S.C. 102(b) as being anticipated by any of Wilkie et al (Genomics, 1993) or Wray et al (Gene 1993) or Burton (Nature, 1993) or Gama et al (Mol. Microbiol., 1992) or Birkeland (Can J. Microbiol., 1994) or Arendt et al (Appl. Environ. Microbiol., 1994) is maintained for reasons of record. Applicant argues that there are no regions of greater than 4 contiguous amino acids that are shared by SEQ ID NO:2 and the cited references and therefore, there are no peptides between 6 and 14 amino acids which can be considered an immunogenic epitope (W. Paul, page 250). This has been considered but not found persuasive. Wilkie et al, Wray et al, Gama et al and Arendt et al teach a protein comprising eight contiguous amino acid residues of SEQ ID NO:2. Burton and Birkeland teach a protein comprising seven contiguous amino acids of SEQ ID NO:2.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1800

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 16, 2002